REMARKS

Reconsideration and withdrawal of the rejections of the claims, in view of the remarks presented herein, is respectfully requested.

Claims 1-2, 22, and 41-42 are amended. The pending claims are claims 1-43. The amendments to the claims made herein are fully supported by the specification as filed. No new matter has been added by way of these amendments.

Amendment claiming the benefit of a prior application

The specification has been amended herein to claim the benefit of a prior nonprovisional application under 35 U.S.C. §120. In particular, this application is a continuation-in-part of U.S. Patent Application Serial No. 11/047,026, for BLOOD COAGULATION TEST CARTRIDGE, SYSTEM AND METHOD, filed January 31, 2005, which in turn claims priority from U.S. Provisional Application No. 60/548,438, filed February 27, 2004. The prior application is commonly owned with the present application, is presently pending, and has Cynthia T. Clague and Douglas D. Nippoldt as common inventors with the present application. A Petition pursuant to 37 C.F.R. § 1.78(a)(3) to Accept an Unintentionally Delayed Claim under 35 U.S.C. § 120 is filed herewith (the "Petition"). In the Petition, the Applicants' state that the entire delay between the date the claim was due under 37 C.F.R. § 1.78(a)(2)(ii) and the date the claim is filed was unintentional. Applicants' submit that the conditions for the above-identified application to receive the benefit of the filing date of the prior-filed applications under 35 U.S.C. § have been met. Therefore, the Examiner is respectfully requested to enter the above-referenced amendment.

Objection to the disclosure

The disclosure has been objected to because the "Reference to Related Application" on page 1 of the specification does not include the serial number of the copending U.S. provisional application referred to therein. In response, the specification has been amended to recite a serial number for the U.S. provisional application.

Double Patenting Rejection

Claims 1-2, 21-23 and 41-43 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1-2, 21, 42, 44-46, 71, 78-79 and 85-86 of co-pending Application Serial No. 10/892,000. Applicant submits that the claims of Application Ser. No. 10/892,000 are pending. Hence, changes may be made to the claims of the present application or to the claims of Application Ser. No. 10/892,000 that negate any need for a double patenting rejection or a terminal disclaimer. If, however, any claims are allowed in the present application or in Application Ser. No. 10/892,000, and if any pending claims of a related application are rejected over such claims, Applicants will respond appropriately to a double patenting rejection at that time.

35 U.S.C. § 102(e) Rejection

Claim 21 has been rejected under 35 U.S.C. §102(e) as being anticipated by Nippoldt, et al. (US 2005/0255601). In response, the applicants respectfully traverse the rejection. An amendment has been presented herein claiming benefit as a continuation-in-part of U.S. Application No. 11/047,026, filed January 31, 2005 which claims priority from U.S. Provisional Application No. 60/548,438, filed February 27, 2004. This is the same application that was published as Nippoldt, et al. US 2005/0255601. The applicants therefore respectfully request that the rejection under 35 U.S.C. §102(e) be withdrawn since the Nippoldt, et al. reference is not prior art to the applicants' claimed invention. Claiming of the benefit of a prior application as a continuation-in-part should not be regarded as acquiescence by the applicants in any rejection based on the Nippoldt, et al. reference.

35 U.S.C. § 103(a) Rejections

First Rejection

Claims 22-40 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Nippoldt, et al. In response, the applicants respectfully traverse the rejection. As set forth above, the present application is a continuation-in-part of Nippoldt, et al. and is therefore unavailable as prior art. The applicants therefore respectfully request that the rejection under 35 U.S.C. §103(a) be withdrawn.

Second Rejection

Claims 1-3, 6, 21-23, 26 and 41-43 have been rejected under 35 U,S,C. 103(a) as being unpatentable over Mpok et al (US 2003/0180824) in view of Bote Bote (WO 03/087817) and Chow (WO 02/063273). In response the applicants respectfully traverse the rejection.

The combination of references cited by the examiner fails to provide a prima facie case of obviousness for the rejection of the claims now pending in the application. Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so. The teaching, suggestion, or motivation must be found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. The combination of the Mpok, et al. and Bote Bote references is not suggested by either of the references. Further, the combination of the Mpok, et al. and Chow references is not suggested by either of the references. In fact, the references would lead the person skilled in the art away from such a combination, not toward it. The teachings of the Mpok, et al., Bote Bote and Chow references are so disparate and contrary that the only way that they could be combined as in the rejection is by the use of the applicants' claims as a template to make the combination by hindsight reconstruction. This is clear error and, therefore, the rejections under 35 U.S.C. 103(a) based on the combination of Mpok, et al., Bote Bote and Chow should be withdrawn.

In particular, the principal reference Mpok, et al. discloses a blood coagulation test that determines coagulation only by the detection of blood clots. "The disadvantages of many of these methods, besides cost and the challenge of operation, include the fact that most do not measure coagulation directly. This has been known to pose accuracy problems in many samples." (Mpok, et al., paragraph 20) By contrast, Bote Bote does not measure coagulation by directly detecting blood clots but instead measures changes in fluid viscosity as indicated by the current used by the motor of the device and rotation speed. More specifically, a blood sample is placed into a small cylindrical-shaped cup, inside of which concentrically rotates a rotor, such that the blood sample and a reactant functioning as a

coagulation activator, occupy a small gap between the rotor and the cup. The rotor first rotates to thoroughly mix the blood and activator. The rotor then rotates until an increase of mechanical friction between the rotor and the cup is detected by increased current to the motor due to blood coagulation or reduction in rotation speed. It should be noted that at no time is a clot detected directly. This is contrary to the teaching of direct clot detection in the Mpok, et al reference. Since the Mpok, et al. reference discredits and teaches away from the Bote Bote reference, those references cannot be combined.

The combination of the principal Mpok, et al. reference and the Chow reference is also not suggested by either of the references. In fact, the references would lead the person skilled in the art away from such a combination. As set forth above, Mpok, et al. discloses a blood coagulation test that only determines coagulation by the detection of blood clots and disparages methods which do not measure coagulation directly by the detection of clots. By contrast, Chow does not measure coagulation by directly detecting clots. In fact, the object in the Chow invention is to measure the intensity of thrombus formation and the thrombotic potential of platelets. It does not measure clotting based on viscosity or fluidity changes when a fluid sample changes from a liquid to a gel form since the activated clot time is not a platelet-specific event. It does not measure activated clot time or detect clots directly. Instead, hemostatic activity of platelets in a biological fluid sample is assessed by monitoring the degree of thrombus formation after cells are exposed to known platelet agonists under low shear stress environment. Sample chambers including rotors configured to produce low shear stress on a test sample are disclosed. The sample chambers and rotors are merely used to apply shear stress to the sample, not to make measurements of clots or clotting time. This is contrary to the teaching of direct clot detection in the Mpok, et al reference. Since the Mpok, et al. reference discredits and teaches away from the Chow reference, they cannot be combined as set forth in the rejection.

Additionally, even if combined, the Mpok, et al., Bote Bote and Chow references do not teach the applicants' invention since they fail to teach key elements of the applicants' invention. For example, independent claim 1 requires "detecting means for detecting a reduction of sweeping movement of the agitator vane. None of the three references discloses this. In the rejection, this element is said to be provided by the Bote Bote reference.

However, on close inspection, there is no vane to be sensed in Bote Bote – the reference describes a frustoconical-shaped rotor element with the same taper and slightly smaller diameter as a cup element with which it concentrically rotates such that there is a small clearance between them. Thus, there is no vane movement to be sensed. Instead, Bote Bote shows a speed sensor sensing on the shaft between the motor and rotor. By contrast, the applicants disclose that an agitator vane sensor is actually sensing the motion of the vanes of the agitator and can take the form of a proximity sensor, inductive sensor, magnetic sensor, metal sensor, and optical sensor disposed at a sensor location with respect to the test chamber. In another example, independent claims 1 and 21 require a cylindrical test chamber having an axis, a diameter and a height defining a volume and an agitator mounted at a pivot point at the axis with an agitator vane adapted to be swept about the pivot point and through the test sample in the test chamber. The structure is not found in the principal Mpok, et al. reference and is instead asserted to be in the Chow reference. However, what the Chow reference discloses is not a test chamber and does not contain an agitator with a vane as those terms are understood in the context of the applicants' invention. The Chow reference refers to the cylindrical chamber as a sample chamber because the sample chamber is not used for testing a blood sample, but rather is used to process a blood sample by applying shear stress to it. Testing of the sample occurs only after the sample is removed from the sample chamber. A cylindrical rotor is driven within the sample chamber to apply shear stress to the blood sample. The cylindrical rotor is not disclosed to have vanes or leaflets. It is instead said to be "configured with a non-uniform curvature on each side" to provide "turbulent flow with multiple acceleration and deceleration zones inside the sample chamber." A dictionary definition of vane is "a thin flat or curved object that is rotated about an axis by a flow of fluid or that rotates to cause a fluid to flow or that redirects a flow of fluid." (Merriam-Webster Online Dictionary). This definition clearly fits the vanes disclosed in the application but does not fit what is being disclosed as a "cylindrical rotor" in the Chow reference.

The independent method claims 41 and 42 similarly require the device to "detect the reduction of sweeping movement of the agitator vane." This method step is not disclosed in the Mpok, et al. and Bote Bote references for the same reason as set forth above – no vane is

being sensed in either Mpok, et al or Bote Bote. Also, the step requiring the device to "sweep the agitator vane about the pivot point through the test sample" is not disclosed in either Mpok, et al. or Chow for the reasons set forth above – they fail to disclose a vane suitably constructed and positioned to do so.

Third Rejection

Claims 4-5, 7-20, 24-25 and 27-40 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Mpok, et al. in view of Bote Bote and Chow as applied to claims 1-3, 6, 21-23, 26 and 41-43, and further in view of Nippoldt, et al. In response, the applicants respectfully traverse the rejection. As set forth above, an amendment has been presented herein claiming benefit as a continuation-in-part of the Nippoldt, et al application. Therefore, the applicants respectfully request that the rejection under 35 U.S.C. §103(a) be withdrawn since the Nippoldt, et al. reference is not prior art to the applicants' claimed invention.

Conclusion

A request for a one month extension of time also accompanies this amendment. Please charge the fees for the extension of time to Deposit Account No. 13-2546.

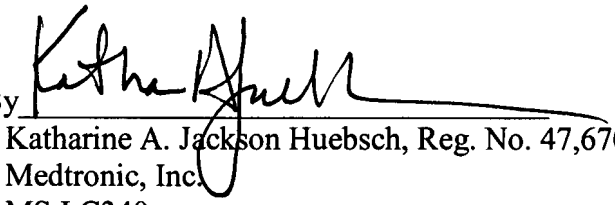
If the Examiner comes to believe that a telephone conversation may be useful in addressing any remaining open issues in this case, the Examiner is invited to contact the undersigned attorney at 763-391-9634.

Please charge any required fees or credit any overpayment to Deposit Account No. 13-2546.

Examination and reconsideration of this application are respectfully requested.

Respectfully submitted,

Date: August 2, 2007

By 

Katharine A. Jackson Huebsch, Reg. No. 47,670
Medtronic, Inc.
MS LC340
710 Medtronic Parkway
Minneapolis, MN 55432
Tel. 763.391.9634
Fax. 763.391.9688
email: katy.j.huebsch@medtronic.com
Customer No. 27581